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June 1, 2018

HIGHLY CONFIDENTIAL—FILED UNDER SEAL

Via ECF
Hon. Michael A. Hammer, U.S.M.J.
Martin Luther King Building
& U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

Re: *Celgene Corp. v. Par Pharm., Inc.*, C.A. No. 2:17-3159-ES-MAH
Celgene Corp. v. Hetero Labs Ltd., C.A. No. 2:17-3387-ES-MAH

Dear Judge Hammer:

This firm, together with Taft Stettinius & Hollister LLP, represents Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex"), and Hetero Labs Limited, Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero"), in the above-referenced 17-3387 action. Pursuant to Your Honor's instruction at the May 11, 2018 status (17-3387 ECF No. 165), we write on behalf of Apotex and Hetero; Defendants Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan N.V. (collectively, "the Mylan Defendants"); Teva Pharmaceuticals USA, Inc. ("Teva"); Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, and Eugia Pharma Specialties Limited (collectively, "Aurobindo"); and Breckenridge Pharmaceutical, Inc. ("Breckenridge") (all defendants collectively, "Defendants"), and Plaintiff Celgene Corporation ("Celgene" or "Plaintiff"), in connection with Defendants' request for leave to file for summary judgment of non-infringement of U.S. Patent No. 8,828,427 B2 ("'427 patent").

DEFENDANTS' POSITION:

I. INTRODUCTION.

Celgene instituted this action alleging that Defendants' ANDAs seeking FDA approval to market 1, 2, 3, and 4 mg capsules of pomalidomide infringe four patents, including the '427 patent, which claims specific capsule formulations of pomalidomide.[1] Defendants respectfully

[1] *See generally*, 17-3159 ECF No. 1, Compl.; 17-3387 ECF No. 1, Compl.; *see also*, Ex. A, '427 patent at claims. Through counterclaims Celgene has asserted five more patents against four of the Defendants—Apotex, Hetero, Breckenridge, and Aurobindo.

request leave to file for summary judgment of non-infringement of the '427 patent, as Defendants have designed around the '427 patent, Celgene concedes no literal infringement, and Celgene is estopped from asserting infringement under the doctrine of equivalents ("DOE") for two independent reasons: (1) Celgene narrowed its claims during prosecution to avoid the prior art ("amendment-based estoppel"), and (2) Celgene made clear and unmistakable arguments which surrendered claim scope beyond the specific capsules claimed in the '427 patent ("argument-based estoppel"). *Spectrum Pharm., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1337 (Fed. Cir. 2015). As the Supreme Court and Federal Circuit have repeatedly held, prosecution history estoppel ("PHE") is a legal issue "to be determined ***by the court***, either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997) (emphasis added); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1323 (Fed. Cir. 2009).

The Supreme Court has further explained that "[e]stoppel is a 'rule of patent construction' that ensures that claims are interpreted by reference to those 'that have been cancelled or rejected.'" *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733 (2002) (citation omitted) ("*Festo USSC*"). As the Parties and the Court will be embarking on claim construction shortly, which will involve consideration of the prosecution histories of the patents-in-suit,[2] Defendants respectfully request that opening and responsive summary judgment briefing parallel the opening (November 15, 2018) and responsive (February 15, 2019) claim construction briefing dates in the Court's Pretrial Scheduling Order, with an additional date for Defendants' reply summary judgment brief.

Judicial economy counsels in favor of granting Defendants leave. The Parties and the Court should not have to spend any time, and Defendants should not have to accommodate the amount of time and expense relating to the discovery that Celgene is proposing in its responsive portion of the letter, taking a patent through discovery for which there are no material issues of fact concerning non-infringement and for which there is a threshold legal issue (PHE) that needs to be decided.

II. DEFENDANTS ARE ENTITLED TO JUDGMENT OF NON-INFRINGEMENT.

A. Celgene Concedes No Literal Infringement.

Celgene asserts that: a) Defendants' 1 mg pomalidomide capsules infringe '427 patent claims 3-4; b) Defendants' 2 mg capsules infringe claims 5-6; c) Defendants' 3 mg capsules

[2] Defendants **will not** be relying upon expert testimony in connection with their opening summary judgment papers. Defendants' grounds for summary judgment are based solely on the prosecution history of the '427 patent. Nevertheless, any argument from Celgene that summary judgment is premature because the Parties have not completed expert discovery is moot as Celgene will be able to include any expert opinions it needs in opposition to summary judgment with any declarations it submits from its experts during claim construction.

infringe claims 7-8; and d) Defendants' 4 mg capsules infringe claims 9-10.[3] [redacted] In its pleadings, Celgene has accused each defendant of "[i]nfringement of the '427 [p]atent,"[5] which includes both literal and DOE infringement. However, Celgene expressly concedes that Defendants' pomalidomide capsules do not literally infringe the asserted claims.[6] Defendants are thus entitled to at least summary judgment of no literal infringement.

B. Celgene Is Estopped from Asserting Infringement under the DOE.

1. Amendment-Based Estoppel.

The '427 patent issued from U.S. Patent Application No. 12/783,390 ("'390 application"). The original claims filed were essentially directed to "oral dosage forms" weighing certain amounts and "compris[ing]: 1) pomolidomide [sic], or a pharmaceutically acceptable salt or solvate thereof, at an amount that provides [1, 2, 3, or 4 mg potency] of pomolidomide [sic]; and 2) a pharmaceutically acceptable carrier or excipient."[7] In response to indefiniteness rejections and obviousness rejections based on the prior art, Celgene narrowed its claims by, *inter alia*, including limitations specifying the required presence of three excipients—pregelatinized starch, sodium stearyl fumarate, and spray dried mannitol—at certain required amounts, and by specifying that the claimed dosage forms were capsules.[8] *See Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139-40 (Fed. Cir. 2004) (adding claim limitations constitutes a narrowing amendment).

These narrowing amendments ***automatically*** trigger a presumption "that the patentee surrendered all subject matter between the broader and the narrower language." *Festo USSC*, 535 U.S. at 740. Celgene can overcome this presumption only by showing: (1) unforeseeability of the alleged equivalent at the time of amendment; (2) the rationale underlying the amendment

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[3] Ex. B, Celgene's '427 patent infringement contentions to Apotex, Hetero, the Mylan Defendants, Teva, Aurobindo, and Breckenridge, respectively.

[4] *See also*, Ex. D, Composition Statements from each defendant's ANDA.

[5] *See, e.g.*, 17-3387 ECF No. 1, Compl. ¶¶ 241-285 and prayers for relief.

[6] *See generally*, Ex. B; *see also*, Ex. E, Status Hr'g Tr. 21:11-14, May 11, 2018.

[7] Ex. F, '390 Application Prosecution History ("'390 PH"), Original Application at 44-48 (CELPOM00001542-46).

[8] *Id.* at April 24, 2012 Office Action at 2-11 (CELPOM00001644-53); *id.* at Aug. 16, 2012 Amendment at 3-5, 7 (CELPOM00001684-86, -88); *id.* at Nov. 15, 2012 Office Action at 2-15 (CELPOM00001791-804); *id.* at Feb. 13, 2013 Amendment at 2-5 (CELPOM00001818-21); *id.* at March 25, 2013 Advisory Action at 1-4 (CELPOM00001834-37); *id.* at June 7, 2013 Supplemental Amendment at 2-4 (CELPOM00001851-53).

bears no more than a tangential relation to the equivalent; or (3) some other reason suggesting that the patentee could not be reasonably expected to have described the equivalent. *Id.* at 740-41. PHE and the rebuttal of any presumption are ***legal issues*** for the Court to resolve (including any underlying factual issues). *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1367-69 (Fed. Cir. 2003) ("*Festo IX*").

In its infringement contentions, Celgene does not rely on exceptions (1) or (3);[9] Celgene only relies on exception (2), arguing that the rationale underlying its narrowing amendments was related to the "ratio of binder to filler," and bears only a tangential relation to the changes Defendants have made.[10] At the outset, the tangential relation exception is to be assessed "very narrow[ly]," *Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1315-16 (Fed. Cir. 2008) ("*Honeywell II*"), and "is ***for the court to determine from the prosecution history record without the introduction of additional evidence***, except, when necessary, testimony from those skilled in the art as to the interpretation of that record," *Festo IX*, 344 F.3d at 1369-70 (emphasis added).

Celgene's arguments regarding the tangential relation exception are incorrect as a matter of law, as the alleged equivalents in Defendants' ANDA [redacted] focus on the specific pregelatinized starch, sodium stearyl fumarate, and spray dried mannitol limitations that Celgene added during prosecution to avoid the prior art. These amendments "bore a direct, not merely tangential, relation to the equivalent[s]." *Honeywell II*, 523 F.3d at 1316. By amending its claims to require very specific amounts of pregelatinized starch, sodium stearyl fumarate, and spray dried mannitol, Celgene was distinguishing all prior art dosage forms of pomalidomide with different amounts of the recited ingredients, or different ingredients altogether, not just a "ratio of binder to filler."[11] *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1383 (Fed. Cir. 2005) ("[Patentee] amended its [precipitated silica claim] to incorporate numerous limitations identifying the specific characteristics that distinguished its invention from the prior art, including the trait that it

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[9] *See generally*, Ex. B. [redacted] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1382 (Fed. Cir. 2007) ("An equivalent is foreseeable if one skilled in the art would have known that the alternative existed in the field of art as defined by the original claim scope, even if the suitability of the alternative for the particular purposes defined by the amended claim scope were unknown.").

[10] *See, e.g.*, Ex. B, Celgene's '427 patent infringement contentions to Apotex at 112.

[11] Ex. F, '390 PH, June 17, 2013 Supplemental Amendment at 7-8 (CELPOM00001856-57) ("[T]here simply is no disclosure in the cited references that would have prompted one skilled in the art to prepare a composition having pomalidomide at the specified amounts, ***along with the particular binders and fillers at the specified amounts***." (emphasis added)).

was 'dust-free and non-dusting.' [The patentee]'s articulation of these characteristics was not limited to the form of the silica produced," and all other forms of silica were "presumptively surrendered."). Any dispute over the rationale for the amendment is a legal issue for the Court to decide. *Festo IX*, 344 F.3d at 1369-70.

2. Argument-Based Estoppel.

In tandem with its narrowing amendments, Celgene argued that the prior art did not disclose its specific capsule formulations as amended,[12] and that its narrowed claims were patentable because the specific ingredients recited gave rise to a capsule formulation that was superior in stability to other pomalidomide dosage forms. Specifically, Celgene argued that, despite 1:1 compatibility tests it carried out showing pomalidomide compatible with a number of excipients, during product development it found that many formulations of pomalidomide were unstable, and that its testing showed "unexpected[ly] . . . that not just any excipients (for example, those listed [in the prior art]) can be combined to provide the favorable stability exhibited by the currently claimed dosage forms."[13] Celgene then submitted a declaration from Anthony Tutino, a named inventor, who presented data allegedly showing that the claimed formulation was more stable than nine other pomalidomide formulations.[14] Based on the Tutino declaration, Celgene argued that "picking any excipients from the list of excipients provided in [the prior art] would not have achieved the stability possessed by the currently claimed pomalidomide dosage forms," and that this "unexpected and superior stability data" established the non-obviousness of the claimed pomalidomide capsules over the prior art.[15] Celgene argued that it was the "***specific excipients at specific amounts*** [which] provide favorable stability [of the claimed dosage forms] required for clinical use."[16]

These statements amount to "clear and unmistakable expressions of [Celgene's] intent to surrender" pomalidomide capsules beyond the specific formulations recited in the claims. *Spectrum*, 802 F.3d at 1338. In *Spectrum*, the applicants argued that their composition claims required a minimum of four grams of the drug, and that the claims "define an aspect of the invention that is of great practical significance." *Id.* This was enough for the Federal Circuit to find surrender for doses smaller than four grams, *id.*, and supports estoppel here. Resolution of whether arguments made during prosecution rise to the level of estoppel is a legal issue for the Court. *Spectrum*, 802 F.3d at 1337; *Mark I Mktg. Corp. v. R. R. Donnelly & Sons Co.*, 66 F.3d 285, 291 (Fed. Cir. 1995).

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[12] *Id.*

[13] *Id.* at 8 (CELPOM00001857).

[14] Ex. F, '390 PH, Decl. by Anthony Tutino at 1-5 (CELPOM00001861-65).

[15] *Id.* at June 17, 2013 Supplemental Amendment at 9-10 (CELPOM00001858-59).

[16] *Id.* at 9 (CELPOM00001858) (emphasis added).

III. NO MATERIAL FACT ISSUES PRECLUDING SUMMARY JUDGMENT.

In its portion of the instant letter, Celgene goes through great lengths to argue that material fact issues preclude summary judgment. These arguments should be rejected.

First, Celgene's argument that Defendants' intention to seek leave to amend their non-infringement contentions "might very well change" the accused equivalents in Defendants' ANDA products (*see* 13-14, *infra*) is a red herring—Defendants only seek to respond to Celgene's DOE arguments, which it raised only after Defendants served their non-infringement contentions. More importantly, Defendants' responses to Celgene's DOE arguments cannot alter Defendants' ANDA products and the features of those products that Celgene alleges are equivalent to missing claim terms. Moreover, Defendants are proposing that summary judgment briefing be concurrent with claim construction briefing, which will not commence until November 15, 2018 (17-3387 ECF No. 123 at 5)—nearly six months from now. Thus, any amendments to the Parties' contentions will be completed well before then, and Celgene's meritless complaints on this issue will be moot.

Second, Celgene's assertion that the rationale underlying its narrowing claim amendments is an issue of material fact precluding summary judgment (*see*, 10, *infra*) is incorrect and contrary to the law. *Festo IX's* instruction that this Court may rely, "when necessary, [on] testimony from those skilled in the art as to the interpretation of [the prosecution history]," *Festo IX*, 344 F.3d at 1369-70, means only that such testimony can be used to help understand scientific concepts in the prosecution history; it does not mean that expert testimony can contradict the plain meaning of the prosecution history. *Merck & Co. v. Mylan Pharm., Inc.*, 19 F. Supp. 2d 334, 351 n.30 (E.D. Pa. 1998), *aff'd*, 190 F.3d 1335 (Fed. Cir. 1999) (rejecting an expert's proffered interpretation of the prosecution history "that would alter the indisputable public record").[17] PHE, including any underlying factual issues, is a legal issue for the court to decide, and the inquiry into the rationale underlying a narrowing amendment (to assess the tangential relation exception) is a "very narrow" one to be decided by the court ***based on the prosecution history alone***. *Festo IX*, 344 F.3d at 1367-69; *Depuy*, 567 F.3d at 1324; *Honeywell II*, 523 F.3d at 1315-16. The Federal Circuit has rejected attempts by patent owners to rely on extrinsic evidence, including expert declarations, to establish the reasons underlying claim amendments or to create fact issues to avoid summary judgment. *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed. Cir. 2003) ("Only the public record of the patent

[17] Celgene's argument that any disagreement between the Parties regarding the meaning of "amount levels" as used in the prosecution history creates a "heighten[ed] . . . need for both fact and expert discovery" (*see* 11, *infra*), which precludes summary judgment, is meritless. As Defendants are requesting summary judgment briefing concurrent with claim construction briefing, where the Parties and the Court will already be interpreting the prosecution history, Celgene is free to submit expert declarations supporting its interpretation of the prosecution history, but resolution of any dispute between the Parties as to its meaning is a "purely legal issue" for the Court to decide via summary judgment. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1254 (Fed Cir. 2000); *Depuy*, 567 F.3d at 1324.

prosecution, the prosecution history, can be a basis for such a reason. Otherwise the public notice function of the patent record would be undermined."); *Bayer*, 212 F.3d at 1254 ("[T]estimony as to what a reasonable competitor would conclude from the prosecution history ***cannot create a genuine issue of material fact so as to bar summary judgment***." (emphasis added)); *Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, No. 13-1632-LPS (consol.), 2017 WL 3723934, at *4-*5 (D. Del. Aug. 29, 2017) ("[E]xpert opinions cannot establish tangentiality or the reason for an amendment."); *Not Dead Yet Mfg., Inc. v. Pride Solutions, LLC*, 265 F. Supp. 3d 811, 832 (N.D. Ill. 2017). This Court and others have granted summary judgment of non-infringement based on PHE, and have rejected related requests for discovery. *AstraZeneca UK Ltd. v. Dr. Reddy's Labs., Ltd.*, No. 08-3237 (MLC), 2010 WL 4721384, at *8-*9 (D.N.J. Nov. 15, 2010); *Aventis Pharm., Inc. v. Barr Labs., Inc.*, 335 F. Supp. 2d 558, 567-74 (D.N.J. 2004); *Intellectual Ventures*, 2017 WL 3723934, at *4-*5.

Third, Celgene's arguments based on *Kyowa Hakka Bio, Co. v. Ajinomoto Co.*, No. 17-313, 2018 WL 834583 (D. Del. Feb. 12, 2018), and the *Hormone Research Foundation v. Genentech, Inc.*, 904 F.2d 1558 (Fed Cir. 1990) ("*HRF*") case it relies on (*see* 11-12, *infra*), should be rejected. *HRF* is an outdated case that was essentially overruled by the Supreme Court in *Warner-Jenkinson*, which held that PHE is a legal issue to be decided by the court via a pretrial summary judgment motion (or post-trial via JMOL after a jury verdict). *Warner-Jenkinson*, 520 U.S. at 39 n.8. *HRF* was also decided before the Supreme Court's *Festo* decision, and before the Federal Circuit applied that decision in *Festo IX* and numerous other cases, unambiguously holding that PHE is a legal issue to be resolved by the court in its entirety, and rejecting attempts by patent owners to rely on expert testimony to create fact issues. *See, e.g.*, *Depuy*, 567 F.3d at 1323-24; *Bayer*, 212 F.3d at 1254; *Spectrum*, 802 F.3d at 1337.

Thus, the Delaware *Kyowa* case relies on bad law. While Celgene appears to concede that whether an amendment is made for patentability reasons is a legal issue, Celgene nevertheless argues, based on *Kyowa*, that the "scope of disclaimer" is a fact issue precluding summary judgment. (*See* 11, *infra*). This finds no basis in Federal Circuit law, or the law of any other District. The only rebuttal factor that Celgene raises in response to Defendants' argument-based estoppel defense is the tangential relation exception, which focuses only on the legal issue of whether the rationale underlying the amendment bears no more than a tangential relation to the equivalent—***there is no "scope" analysis***. If the tangential relation exception is not established (as is the case here), PHE completely bars resort to the DOE, and the claim is not entitled to any equivalents. *Festo USSC*, 535 U.S. at 740-41; *Honeywell II*, 523 F.3d at 1315 ("If the prosecution history reveals no reason for the narrowing amendment, [or if it reveals a reason not tangential to the equivalent], the presumption [of estoppel] is not rebutted."). In fact, the language from *Kyowa* that Celgene relies is directly contradicted by the Delaware court's earlier pronouncement on the law of PHE: "expert opinions cannot establish tangentiality or the reason for an amendment." *Intellectual Ventures*, 2017 WL 3723934, at *5.

Fourth, Celgene's argument that summary judgment prior to expert discovery would deprive it of the opportunity to present expert testimony "based, in part, on the factual record" (*see* 12-13, *infra*) ignores the Federal Circuit's mandate that this Court must decide the tangential

relation exception to PHE "from the prosecution history record without the introduction of additional evidence." *Festo IX*, 344 F.3d at 1370. Thus, testimony from Mr. Tutino that Celgene would like its experts to rely on—presumably to explain away arguments Mr. Tutino made during prosecution which support estoppel—is irrelevant to PHE and would not preclude summary judgment. *Aventis*, 335 F. Supp. 2d at 572 (rejecting request for more discovery); *Intellectual Ventures*, 2017 WL 3723934, at *4-*5 (same).

Fifth, and finally, Celgene's argument that consideration of Defendants' ANDAs warrants a narrow application of PHE under the "reasonable competitor" standard (*see*, 13, *infra*) is based on the legally erroneous premise that Defendants' ANDAs may be considered in assessing PHE, and should be rejected. *Pioneer*, 330 F.3d at 1356; *Bayer*, 212 F.3d at 1254.

IV. CONCLUSION.

Defendants respectfully request leave to file for summary judgment of non-infringement of the '427 patent with their opening claim construction papers.

* * *

PLAINTIFF'S POSITION:

I. INTRODUCTION

This Hatch-Waxman patent-infringement case involves nine patents-in-suit (including the '427 patent) and six defendants. The '427 patent contains only 8 of the 239 asserted claims in this case. The claims of the '427 patent are directed to formulations containing pomalidomide. Celgene's Pomalyst® drug product is an embodiment of the asserted claims of the '427 patent.

Defendants' request for leave to file an early summary judgment motion for non-infringement of the '427 patent should be denied for several reasons. Defendants' legal theories are wrong, and several material facts are in dispute.[18] Moreover, the 30-month stay of FDA approval of Defendants' ANDAs does not expire until August of 2020. Celgene respectfully submits that there is no urgency that warrants the Court deciding Defendants' infringement of the '427 patent on the present, undeveloped record, especially given the statutorily-granted time to resolve this case. And given the eight other patents-in-suit, Defendants' proposed motion would be far from case dispositive even if it were decided in Defendants' favor.

Furthermore, Defendants recently disclosed that they intend to move to amend their non-infringement contentions. The prosecution history estoppel ("PHE") analysis on which Defendants' motion rests entails consideration of the accused equivalent. Here, the accused equivalent might very well change if Defendants' motion to amend their contentions is granted. Defendants' argument to the contrary lacks merit, as Defendants cannot claim to know how

[18] To the extent that Defendants take the position that the facts Celgene raises are not in dispute, then Defendants have no good-faith basis to pursue their non-infringement theories.

Celgene may amend its contentions after it has seen and considered Defendants' new positions. This further cuts against consideration of an early summary judgment motion. Defendants' request is premature at best, and should be denied for this additional reason.

II. LEGAL STANDARDS

"In order for prosecution history estoppel to apply[,] there must be a deliberate and express surrender of subject matter." *Kyowa Hakka Bio Co. v. Ajinomoto Co.*, No. 17-313, 2018 WL 834583, at *6 (D. Del. Feb. 2, 2018) (citing *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1580 (Fed. Cir. 1995)) (denying motion to dismiss for non-infringement due to "factual questions" regarding PHE). The applicants made no such surrender during prosecution of the '427 patent. And even if the Court were to apply a presumption that amendments made during prosecution amounted to such a surrender, "the patentee can rebut the presumption of surrender by showing," among other things, "that the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question." *Honeywell Int'l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1145 (Fed. Cir. 2004) (remanding to district court for findings on this and other issues) (internal citations and quotations omitted).

Summary judgment is proper only where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment is a drastic remedy and is therefore granted cautiously. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). The moving party bears the burden of showing the absence of genuine issues of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The Supreme Court has cautioned that there must be "adequate time for discovery" before such a burden can be met. *See id.* In evaluating a motion for summary judgment, the Court may not make credibility determinations or weigh the evidence. *Metropolitan Life Ins. Co. v. Bancorp Serv.*, LLC, 527 F.3d 1330, 1338-39 (Fed. Cir. 2008).

III. ARGUMENT

A. Disputed Material Facts Exist Regarding The Existence And Extent Of Any Estoppel

Contrary to Defendants' assertion, the applicants of the '427 patent did ***not*** surrender any subject matter during prosecution. Defendants argue that PHE bars Celgene from asserting infringement under the doctrine of equivalents because the applicants allegedly narrowed the claims of the '427 patent during prosecution by: (1) "specifying the required presence of three excipients—pregelatinized starch, sodium stearyl fumarate, and spray dried mannitol—at certain required amounts, and by specifying that the claimed dosage forms were capsules"; and (2) arguing to the patent office that it was those specific ingredients, at those specific amounts, that gave rise to the "superior stability to other pomalidomide dosage forms."

As Defendants acknowledge, however, Celgene contends that any amendments and arguments made during prosecution were, at most, tangential to the accused equivalents.

Celgene also disputes that the scope of any purported, surrendered subject matter is as broad as Defendants contend.

Quoting *Festo IX*, Defendants claim that Celgene's "tangential exception" contentions are:

> ***for the court to determine from the prosecution history record without the introduction of additional evidence***, except, when necessary, testimony from those skilled in the art as to the interpretation of that record.

Festo IX, 344 F.3d at 1369-70 (emphasis added). Defendants' emphasis on only part of this quote is telling and exposes the flaw in their analysis. Specifically, Defendants bold the portion of the quote that they apparently believe supports resolving these issues on summary judgment. Yet they entirely ignore the critical language that Celgene has underlined above regarding the need for interpretation of the file history in this case, including by those skilled in the art.

Defendants incorrectly contend that Celgene surrendered ***all*** subject matter except specific amounts of specific ingredients. Properly considered, the prosecution history shows that any amendments and arguments made during prosecution related to the "amount levels," or ***ratios***, of binder (starch) to filler (mannitol) in the claimed inventions. (*See, e.g.*, Ex. 1, Celgene's Infringement Contentions to Hetero at 111.) Accordingly, to the extent that there is any PHE at all, Celgene did not disclaim the claimed ratios of mannitol to starch (and equivalents thereto). Sodium stearyl fumarate (the other ingredient on which Defendants focus) is not a binder or filler and, thus, is not relevant to any PHE arguments. (*See id.*)

[redacted] Defendants seek to avoid infringement, by arguing that:

> Celgene was distinguishing ***all*** prior art dosage forms of pomalidomide with ***different amounts*** of the recited ingredients, or different ingredients altogether, not just a "***ratio*** of binder to filler."

This is a material fact in dispute, the resolution of which will be based on other disputed material facts. In other words, in addressing the infringement issues in this case, the Court must resolve whether Celgene disclaimed other lubricants and all other amounts of the claimed binder and filler—as Defendants contend—or if Celgene disclaimed only amounts of binder and filler that did not fall within the claimed ratio of mannitol to starch (and equivalents thereto)—as Celgene contends. Thus, the Court must determine the scope of any PHE, to the extent there was any at all. As explained below, resolution of this dispute will involve fact and expert discovery. Thus, material facts are in dispute, and summary judgment is inappropriate. Defendants' efforts to rush to judgment regarding their infringement of the '427 patent on an undeveloped record

that does not yet include any discovery on these disputed factual issues would serve only one purpose—to unfairly prejudice Celgene.

First, remarks made by the applicants in response to an office action during prosecution of the '427 patent support Celgene's ratio contention. Specifically, the response to the office action states that it was "unexpected" that the "amount ***levels***" of the binder and filler "would bring about any advantageous properties in combination with Pomalidomide." (Ex. 2, 8/16/12 Response to Office Action at 9-10 (emphasis added).) Before this Court can resolve infringement of the '427 patent, the parties need to engage in discovery on this disputed issue. For example, Celgene intends to introduce evidence that one of skill in the art would understand "amount ***levels***" to be referring to ratios of binder to filler, and not to any specific amounts of either, and not to any lubricant. *See Festo IX* at 1369-70 (recognizing the need for expert testimony to interpret disputed portions of the file history); *Hormone Research Foundation, Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1567 (Fed. Cir. 1990) (vacating and remanding summary judgment of non-infringement based on PHE because different "possible interpretations" of arguments during prosecution presents a "factual question" that "precludes summary judgment").

Defendants argue that expert testimony is inappropriate because "such testimony can [only] be used to help understand scientific concepts in the prosecution history; it does not mean that expert testimony can contradict the plain meaning of the PHE." But to the extent that Defendants disagree that "amount levels" refers to ratios (and, instead, means specific amounts of each ingredient), then the prosecution history does not have a "plain meaning." As explained below, both the inventor declaration submitted during prosecution and the specification of the '427 patent focus on ratios of binder to filler as the claimed invention, and the claims cover those ratios. This further supports Celgene's position. At the very least, it adds to any ambiguity present in the intrinsic record, heightening the need for both fact and expert discovery.

The cases that Defendants rely upon—holding that PHE is an issue of law—do not stand for the proposition that there can never be a disputed issue of material fact with respect to PHE. Instead, the cited cases hold that the ***reason or rationale*** for amendments made during prosecution, and whether any PHE should apply in the first place, are issues of law that do not require expert discovery. *See Merck*, 19 F.Supp. at 351 n.30 (rejecting consideration of expert report where there was an unambiguous amendment, but patentee argued the amendment was made for restriction, not patentability, purposes, and the expert repeated that argument); *Pioneer*, 330 F.3d at 1356 ("[W]e do not consider the Beecher declaration in determining the reason for the amendment to the claim"); *Intellectual Ventures*, 2017 WL 3723934, at *5 (noting that expert opinion cannot supply the "reason" for the amendment); *Not Dead Yet*, 265 F. Supp. 2d at 832 (rejecting expert opinion concerning whether statements constituted disclaimer as opposed to "isolated statements" unrelated to patentability). Celgene, however, is not relying on material facts relating to the ***reason or rationale*** for any amendment made during prosecution. Instead, Celgene is relying on material facts relating to the ***scope*** of disclaimer (if any) that any claim amendment may have introduced. Defendants' cited cases are silent on this issue, and do not demonstrate that the scope of any PHE can be decided as a purely legal issue. Defendants' cases are, therefore, inapplicable to the disputed material factual issues at hand, and they do not address the need for fact and expert discovery in this case. In contrast, the cases cited by

Celgene (e.g., *Festo IX*, *Hormone Research*, *Kyowa*) clearly demonstrate that fact and expert discovery appropriately aid in determining the scope of any disclaimer and in resolving ambiguity in the intrinsic record.

Defendants also incorrectly argue that *Hormone Research* is "an outdated case that was [(1)] essentially overruled" by *Warner-Jenkinson* in 1997; and (2) decided before the Federal Circuit applied *Warner-Jenkinson* in *Festo IX* in 2003. *Hormone Research* was cited and followed as recently as February 2018 by the District of Delaware to deny an early motion regarding PHE because "the scope of estoppel depends on ***factual questions*** regarding the prosecution history, which may ***preclude a disposition of the issue*** not only on a motion to dismiss, but ***on summary judgment***." *Kyowa*, 2018 WL 834583, at *6 (emphasis added). This directly supports Celgene's position that disputed issues of material fact related to the scope of any estoppel cannot be resolved on summary judgment. And contrary to Defendants' implication, different possible interpretations of arguments made during prosecution preclude summary judgment on the issue of alleged PHE.

Finally with respect to this issue, Defendants' offer to allow Celgene to introduce expert testimony in the context of claim construction proceedings (*see* n.2) is unworkable and prejudicial to Celgene. As explained below, such expert testimony will be based, in part, on the factual record. Celgene should be allotted "adequate time for discovery" to develop that factual record. *See Celotex*, 477 U.S. at 323. As such, expert testimony cannot be offered during the claim construction phase.[19] Moreover, Defendants' statement that they will not rely upon expert testimony "in connection with their ***opening*** summary judgment papers" (n.2 (emphasis added)) is particularly troubling. Defendants are hedging on whether competing expert opinions will result, perhaps through expert testimony submitted with Defendants' ***reply*** papers. Competing expert testimony defeats summary judgment. *See, e.g.*, *Metropolitan*, 527 F.3d at 1338-39 (vacating summary judgment of non-infringement because of "a direct conflict in the declarations as to a material fact under [one party's] interpretation of the claims"); *In re Gabapentin Patent Litig.*, 395 F. Supp. 2d 175, 180 (D.N.J. 2005) (finding that conflicting expert reports created disputed issues of material fact).

Second, Defendants apparently intend to rely upon a declaration submitted during prosecution by one of the '427 patent's inventors, Dr. Anthony Tutino, in support of their motion for summary judgment. Celgene will introduce factual testimony from Dr. Tutino himself regarding the claimed inventions. Celgene should also, for the reasons stated above, be afforded the opportunity to introduce expert testimony regarding one of ordinary skill's interpretation of Dr. Tutino's declaration and testimony. Again, disputed issues of material fact will result from this evidence.

For example, Defendants argue that Dr. Tutino's declaration limits the claims to specific amounts of specific ingredients. Defendants ignore, however, that Dr. Tutino's discussion in his

[19] Defendants also proposed several terms from the '427 patent for construction, which may affect Celgene's infringement arguments—and, in turn, the PHE arguments—in this case.

declaration of "Formulation F, *i.e.*, [the] formulation claimed" (Ex. 3, 6/14/13 Declaration of Anthony Tutino, at 4), does not support Defendants' desired limitations. Rather, Dr. Tutino's declaration demonstrates that Formulation F contains a different ingredient—croscarmellose sodium. (*Id.* at 3.) In other words, the "formulation claimed" is not limited to pregelatinized starch, spray-dried mannitol, and sodium stearyl fumarate, as Defendants allege. (*See id.*) Likewise, Formulation F does not have the specific amounts of ingredients to which Defendants argue the claims should be limited. Rather, Formulation F—consistent with Celgene's ratio contention—has a ratio of mannitol to starch of 1:1.1. (*See id.* (reporting 50% starch and 43.35% mannitol in Formulation F).) The '427 patent's specification also states that the "ratio of mannitol:starch in the dosage form is from about 1:1 to about 1:1.5" (Ex. 4, '427 patent at 7:1-2), and the ratio of mannitol to starch in the claims falls within that range (*id.* at claims). All of these facts disprove Defendants' PHE argument. At a minimum, they create disputed issues of material fact.

Third, even assuming that any PHE exists—it does not—Defendants' ANDAs also demonstrate that the scope of any alleged PHE would be extremely narrow. Determining whether and what subject matter was surrendered "depends on what a competitor, reading the prosecution history, would reasonably conclude was given up by the applicant." *Insituform Techs. v. Cat Contracting, Inc.*, 99 F.3d 1098, 1107-08 (Fed. Cir. 1996). Defendants are Celgene's competitors here. [redacted]

This is actual evidence of competitors trying, but failing, to design around what is claimed in the '427 patent.[20] Defendants' failures to avoid infringing the '427 patent constitute evidence of what a reasonable competitor would think was surrendered (if anything). Celgene intends to further develop this evidence with both: (1) fact discovery, including at least through interrogatories and fact depositions, and then (2) expert discovery, including testimony regarding how an ordinarily skilled artisan would interpret Defendants' ANDAs and the factual evidence related thereto. Thus, this case is unlike the *Bayer* case cited by Defendants. In *Bayer*, the Federal Circuit rejected expert testimony from a "professor of patent law" relating to how one

[20] Of course, Defendants dispute all of this, as they must. If they accepted it, they would have to stipulate to infringement of the '427 patent and their motion for summary judgment would be baseless for this additional reason. That they dispute these material facts undermines their assertion that infringement is ripe for summary judgment.

would interpret the file history in question. *See* 212 F.3d at 1251, 1254. The *Bayer* court did not reject factual evidence from an actual competitor (and then a scientific expert's interpretation of that factual evidence). Defendants' reliance on *Bayer* is, therefore, misplaced.

For the foregoing reasons, even if there is any PHE, the scope of that estoppel will be affected by several material facts in dispute that preclude summary judgment. *See Kyowa*, 2018 WL 834583, at *6 ("[T]he scope of estoppel depends on factual questions regarding the prosecution history, which may preclude a disposition of the issue not only on a motion to dismiss, but on summary judgment.").

B. Defendants' Intent To Move To Amend Their Non-Infringement Contentions Precludes A PHE Analysis

On May 23, 2018, Defendants notified Celgene of their intention to move to amend their non-infringement contentions. (*See* Ex. 7, 5/23/18 e-mail from K. Reichenbach to F. Calvosa.) As explained above, a presumption that an amendment during prosecution resulted in estoppel can be rebutted by showing that "the rationale underlying the narrowing amendment bore no more than a tangential relation to ***the equivalent in question***." *Honeywell*, 370 F.3d at 1145 (emphasis added). Celgene's infringement contentions accused certain aspects of Defendants' ANDA Products as "equivalents" based on allegations in Defendants' original December 15, 2017 non-infringement contentions. But if Defendants are granted leave to amend their non-infringement contentions, Celgene will likely then need to amend its own infringement contentions in response to Defendants' new positions. In those amended contentions, Celgene may need to accuse other aspects of Defendants' ANDA Products as "equivalents." In other words, "the equivalent in question," and therefore the "tangential relation" analysis, remains subject to change. Defendants' argument that their "responses to Celgene's DOE arguments cannot alter . . . the features of [their ANDA] products that Celgene alleges are equivalent" is baseless. Defendants cannot claim to know how Celgene may amend its contentions after it has seen and considered Defendants' new positions. For this additional reason, undertaking a PHE analysis at this time is premature.

C. Literal Infringement Is Not At Issue For The '427 Patent

Defendants also argue that they are "entitled to summary judgment of no literal infringement." As Defendants note, however, Celgene is not asserting literal infringement for the '427 patent. Accordingly, there is no relief to be had on this non-issue.

IV. CONCLUSION

For the foregoing reasons, Celgene respectfully requests that the Court deny Defendants leave to file for summary judgment of non-infringement of the '427 patent.

* * *

Thank you for your attention to and consideration of this request.

Respectfully submitted,

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Respectfully submitted,

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Attachments
Cc: All Counsel of Record (w/attachments)(via email)